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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,821	03/29/2001	Andrew A. Welcher	01017/36938A	6210

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,821	WELCHER ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10,51-55,70,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-8, 10, 51-55, 70, 72-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/2006 has been entered.

Previous claims 1, 4-8, 10, 51-55, 70, 72, and new claim 73 (4/13/2006) are pending and under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 4/13/2006 is acknowledged.

3. Applicant's arguments filed on 4/13/2006 have been fully considered and were non-persuasive. The issues remaining and new issue are stated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 U.S.C. 101

5. Claims 1, 4-8, 10, 51-55, 70, 72-73 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02), pages 3-9 of the previous Office action (12/4/03), pages 2-4 of the previous Office action (7/13/2004), pages 2-7 of the previous Office action (3/14/2005) and pages 2-8 of the previous Office action (10/13/2005).

Applicants argue that page 112, Example 3 of the specification establishes an elevated level of expression of a novel human gene, agp-96614-a1 in human testis. This gene product is indeed novel and unobvious but not patentable because the product does not fulfill the utility requirement for patentability. One of skill in the art, from the disclosure of the instant specification would not recognize a specific and substantial biological role for a novel testis-specific protein. Firstly, the claimed mRNA is not elevated exclusively in testis but also in the pancreas, a colon adenocarcinoma cell line (CX-1), and an ovarian carcinoma cell line (GI-102). Applicants have failed to disclose a specific, substantial and well-established utility for the claimed nucleic acid in the instant specification.

Applicants argue that the claimed nucleic acid can be used as a tissue-specific marker for detecting testis cells. However, contrary to Applicants arguments, any testis-specific gene can be used a tissue-specific marker and with regard to diagnosis of disease, in order for a polynucleotide or protein to be useful, for diagnosis of a disease such as cancer, there must be a well-established or disclosed correlation or relationship between the claimed polypeptide and a disease or disorder. The predominant presence of a polynucleotide in the testis as well as placenta is not sufficient for establishing a utility in diagnosis of a testis-specific protein in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA or protein and the levels in the testis. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only

in eg. cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. over expression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease such as cancer. However, in the absence of any disclosed relationship between the polynucleotide or the polypeptide that is encoded thereby and any disease or disorder and the lack of any correlation between the polynucleotide or the encoded polypeptide with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself.

Applicants argue that prostate-specific antigen (PSA) is a protein which is preferentially expressed in the prostate and has proven to be a very useful human tissue-specific marker for detecting prostate abnormalities, either as an indicator of prostate cells which have moved outside of the prostate as a tumor (i.e., metastatic prostate cancer) or as an elevated level of PSA in the bloodstream, which can indicate the presence of prostate cancer or benign prostatic hyperplasia and have cited Mulders et al., 1990, in this regard. However, contrary to Applicants arguments, the instant nucleic acid is not organ-specific because Applicants have failed to demonstrate that the nucleic acid is expressed at elevated levels exclusively in the testis or that there is an increased level of expression of the claimed nucleic acid in testicular cancer cells. Furthermore, PSA is exclusively present in normal prostatic tissue and in benign prostatic hypertrophy and monitoring serum PSA concentrations by serial measurement (see Mulders et al, page 37, abstract) is useful for the detection of residual or recurrent tumor after primary treatment and for the evaluation of response to systemic treatment of advanced disease, because PSA is exclusive to the prostate. There is no exclusivity or organ-specific expression of the

claimed nucleic acid and therefore, even an implicit disclosure of the claimed subject matter as a marker to testicular cell dissemination or metastasis would not be recognized by one of skill in the art from the disclosure of the instant specification.

Applicants argue that "Northern blot analysis of the MTE blots (Clontech, CA) indicated that agp-96614-a1 was expressed predominantly in human testis". See specification at page 112, lines 13-17. Therefore, Applicants argue that a comparative analysis of the expression of the claimed nucleic acid was summarized in the specification, and drawings (e.g., a Northern blot) are not required in a patent application if they are not necessary for an understanding of the subject matter of the invention. 37 C.F.R. 1.81. Furthermore, Applicants argue that the multiple tissue expression (MTE) blots (Clontech) used in the gene expression experiments described in the specification (see pages 112-114), contained 76 poly A+ RNAs and provided a virtual whole body image of gene expression in all tissues of the body with predominant expression of the claimed nucleic acid in the testis. However, applicants are misinterpreting and misconstruing the Examiner's arguments. Contrary to Applicants arguments, the Examiner is not requiring a different form for disclosing results. The issue here is that the Northern blot analysis of the MTE blots demonstrates that the claimed nucleic acid is expressed "predominantly" in the human testis, pancreas, etc. (see page 112, lines 13-17). Applicants are arguing exclusive and tissue-specific expression in the testis when the specification states otherwise. Therefore, the claimed nucleic acid cannot be used as a marker for disseminated testicular cells because the nucleic acid is also detected in pancreas, colon and ovarian cells. The claimed nucleic acid cannot be used to detect exclusively testis cells because all these other cells,

i.e. pancreas, colon and ovarian cells, which expressed the nucleic acid would also be candidate tissues.

Applicants argue that the Northern blots indicates that the claimed nucleic acid is expressed predominantly in the testis but PCR analysis detected the nucleic acid in the testis, pancreas and in two ex vivo cell lines. Applicants also argue that PSA immunoreactivity has been reported in seminal vesicle epithelium and in non-prostatic tumors of the salivary gland, breast, kidney, bladder, colon and lung. However, contrary to Applicants arguments, the issue here is that at the time of filing of the instant invention, one of skill in the art, from the disclosure of the instant specification would fail to recognize the utility of the claimed nucleic acid as a testis-specific marker. An asserted utility must meet the three-pronged test of being credible, specific and substantial. Firstly, on page 9-10 of the specification, no assertion of using the claimed nucleic acid as a tissue-specific marker is recited. The specification asserts the following as utilities for the claimed polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO:1:

1. use of the nucleic acid to treat, prevent, ameliorate and detect disorders;

2. diagnosing a pathological condition or susceptibility to a pathological condition; and

3. methods of identifying antagonists or agonists of CD20/IGE-receptor like biological activity.

There is no asserted utility in the instant specification of using the claimed nucleic acid as a tissue-specific marker. Therefore, the present arguments of the utility that the claimed nucleic acid is expressed in a tissue-specific manner was obtained only from the teachings of subsequent publications by Ishibashi et al (2001), Liang et al (2001) and Hulett et al (2001). Previously, Applicants were arguing chromosome marker for chromosome 11 (11q12-13) as the utility of the

instantly claimed nucleic acid (see pages 7-8 of Applicants arguments of 9/26/03). The skilled artisan had to conduct significant further research to determine the particular biological functions of the instant nucleic acid in order to identify a specific and substantial utility for this novel nucleic acid. Therefore, one of skill in the art, as of the filing of the instant application, would not have discerned the role of the claimed nucleic acid, because there is no disclosure in the instant specification suggesting what type of exclusive role is played by the claimed nucleic acid.

Claim rejections-35 USC § 112, first paragraph

6. Claims 1, 4-8, 10, 51-55, 70 and 72-73 are also rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02), pages 3-9 of the previous Office action (12/4/03), pages 2-4 of the previous Office action (7/13/2004), pages 2-7 of the previous Office action (3/14/2005) and pages 2-8 of the previous Office action (10/13/2005).

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim rejections, 35 U.S.C. § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73, line 2, is rejected as vague and indefinite because it recites "agp-96614 messenger RNA". It is unclear what this term indicates or if agp-96614 is the term for the protein because the specification page 110, recites "cloning of a CD20/IgE-receptor like cDNA (AGP-96614-a1)". It is suggested that this term be deleted from the claim.

Furthermore, claim 73 is unclear because it fails to recite that the nucleic acid to be used as a probe is labeled. Applicants are reciting a possible use for the claimed nucleic acid but such should be recited in a method claim in which the method for detection uses the nucleic acid as a hybridization probe.

Conclusion

No claim is allowed.

Claims 1, 4-8, 10, 51-55, 70, 72-73 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
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